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## State Water Resources Control Board

# FINAL REGULATION ORDER

## ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

### REGULATIONS

Set forth below are the proposed amendments to title 22 of the California Code of Regulations. The final proposed regulatory language subject to comment in this rulemaking are shown in underline to indicate additions and ~~striethrough~~ to indicate deletions.

E. JOAQUIN ESQUIVEL, CHAIR | EILEEN SOBECK, EXECUTIVE DIRECTOR

**Title 22, CALIFORNIA CODE OF REGULATIONS**

**Division 4, Chapter 19**

**Article 1. Definitions.**

**Amend Section 64801 as follows:**

**Section 64801.00 Definitions.**

The definitions listed in 2016 TNI Standard – Revision 2.1, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis, herein incorporated by reference, apply throughout this chapter. Definitions used differently or that do not exist in 2016 TNI Standard – Revision 2.1, Volume 1, are defined below.

~~(a) "Alternate Test Procedure" means an analytical test method, or procedure that is different in technic from the method(s) cited in Section 64811(a), (b), or (c), but detects and quantifies to the same degree of precision, accuracy, and level of detection.~~

~~(b) "Auxiliary Laboratory Facility" means any stationary place which:~~

~~(1) is operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination; and~~

~~(2) performs analyses in one or more of the same auxiliary; and Field(s) of Testing as the laboratory to which it is auxiliary; and~~

~~(3) is under the supervision of the same Laboratory Director as the laboratory to which it is auxiliary; and~~

~~(4) only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and~~

~~(5) is located such that the transport of samples to the auxiliary laboratory does not affect the quality of the analytical results.~~

~~(c) "A Complete Application" means a verified application for certification containing all the information required in Section 64805(a) or (b), and utilizing ELAP form 001 (dated 1/1/93).~~

~~(d) "Contact Person" means an individual designated by the Laboratory Director to act as a contact between the laboratory and the Department for purposes of exchanging information between the Department and the laboratory.~~

~~(e) "Laboratory" shall have the same meaning as given in Health and Safety Code Section 1010(c)(2).~~

~~(f) "Laboratory Director" means the person who, for the laboratory and its auxiliary or mobile laboratories, if any, is in charge of all analytical and operational laboratory activities; supervises all personnel, including those designated as Principal Analysts; and is the person responsible for the quality of reported data.~~

~~(g) "Facility or Facilities" means fixed or portable building(s), which contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the Field(s) of Testing for which a laboratory is certified accredited, and includes storage areas.~~

~~(h) "Mobile Laboratory" means a vehicle, vessel, aircraft, or trailer, which is certified under Field of Testing 23, and is operated by the same owner as a certified stationary laboratory, and which is designed and equipped for the purpose of transporting and using laboratory equipment to perform analyses in one of the Fields of Testing for which the stationary laboratory is certified.~~

~~(i) "Owner" means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.~~

~~(j) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with these regulations or the statutes under which these regulations are adopted.~~

~~(k) "Principal Analyst" means a person who either supervises the activities of others in, or conducts, the analyses of environmental samples using sophisticated laboratory instruments. For these purposes, "sophisticated laboratory instruments" means: gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma spectrometers (ICP), direct current plasma spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), or high pressure liquid chromatographs (HPLC).~~

~~(l) "Stationary Laboratory" means a laboratory that is permanent and nonmovable and may include fixed in place vehicles.~~

~~(m) "Trade Secret" means any information that meets the definition in Section 6254.7(d) of the Government Code.~~

~~(n) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.~~

~~(o) "Utility Owned" means laboratories owned and operated by federal, state, city, or county agencies.~~

~~(p) "Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track. This definition is the same as the definition as given in Section 670, Vehicle Code.~~

~~(q) "Verified Application" means that the truth and accuracy of the information in the application has been attested to by the signature of a laboratory Owner.~~

~~(r) "Vessel" includes ships of all kinds, steamboats, steamships, canal boats, barges, sailing vessels, and every structure adapted to be navigated from place to place~~

~~for the transportation of merchandise or persons. This definition is the same as given in Section 21, Harbors and Navigation Code.~~

(a) "Acceptable Scores" means analytical results for a Proficiency Testing sample are within the specified acceptance criteria for that sample.

(b) "Accreditation" means the recognition of a laboratory by ELAP to conduct analyses of environmental samples for Regulatory Purposes.

(c) "Assessment Agency" means ELAP or any entity that is contracted by ELAP to conduct laboratory assessments for ELAP.

(d) "CA-NV/AWWA" means California-Nevada Section of the American Water Works Association.

(e) "Citation" means a monetary fine assessed to a laboratory due to non-compliance with a statute, regulation, or order issued or adopted pursuant to the Environmental Laboratory Accreditation Act.

(f) "Client" means the entity for which the laboratory is performing analyses for Regulatory Purposes.

(g) "Complete Application Package" means an application package containing all the elements required in Section 64802.00.

(h) "Corrective Action Plan" means the response to an onsite assessment report that contains a Root Cause Analysis of the finding(s) identified in the onsite assessment report, the corrective actions that will take place to address the findings, and the date by which the finding(s) will be corrected.

(i) "CWEA" means California Water Environment Association.

(j) "Days" means calendar days, unless otherwise stated.

(k) "Denial" means a decision to reject an application for accreditation due to non-compliance with ELAP statutes and regulations.

(l) "ELAP" means the California Environmental Laboratory Accreditation Program, a program within the State Water Resources Control Board.

(m) "Field(s) of Accreditation" means the matrix, technology/method, and analyte combinations for which ELAP will offer accreditation, as defined in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, herein incorporated by reference.

(n) "Owner" means a public agency, or any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

(o) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act on its behalf for purposes of complying with ELAP regulations or the statutes under which ELAP regulations are adopted.

(p) "Primary Accreditation Body" means the organization that actually executes the accreditation process, including but not limited to, receiving and reviewing applications, supporting documents, Proficiency Testing sample results, and conducting on-site assessments or reviewing on-site assessment reports.

(q) "Quality Manager" means a member of the laboratory staff who is responsible for ensuring the management system related to quality is implemented and followed at all times. Where staffing is limited, the Technical Manager and Quality Manager may be the same person.

(r) "Quality Manual" is defined in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, herein incorporated by reference, and replaces the term Quality Assurance Manual.

(s) "Regulatory Purposes" is defined in Health and Safety Code section 100825.

(t) "Revocation" means the permanent loss of a certificate of accreditation due to non-compliance with ELAP statutes and regulations.

(u) "Root Cause Analysis" means an investigation by the laboratory to determine the underlying cause(s) of a finding identified in an onsite assessment report or a non-compliance identified by the laboratory.

(v) "Sophisticated Technology" means analytical instruments, detection systems, and/or preparation techniques requiring an advanced level of user understanding including gas chromatography/mass spectrometry (GC/MS), inductively coupled plasma spectrometry (ICP), inductively coupled plasma/mass spectrometry (ICP/MS), liquid chromatography/mass spectrometry (LC/MS), atomic absorption spectrophotometry (AA), gas chromatography (GC), alpha particle or gamma ray spectrophotometry, electron microscopy (EM), polarized light microscopy (PLM), high pressure performance liquid chromatography (HPLC), bioanalytical assays, and advanced molecular methods.

(w) "State Regulatory Agencies" means those state agencies whose statute or regulations require it to use laboratories that have been accredited by ELAP.

(x) "State Water Board" means the California State Water Resources Control Board, which includes ELAP.

(y) "Suspension" means the total or partial removal of a laboratory's accreditation to allow the laboratory to correct findings that identified non-compliance with ELAP statutes and regulations.

(z) "Technical Manager" is described in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.1.7.2, herein incorporated by reference (with the exception of part [f]), and replaces the title of Laboratory Director.

(aa) "TNI" means The NELAC Institute.

(bb) "Trade Secret" means any information that meets the definition in Government Code section 6254.7(d).

(cc) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of

its weight rests upon any other vehicle. This definition is the same as the definition given in Vehicle Code section 630.

Note: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1010, 1014 and 1017, Health and Safety Code; Section 6254.7(d), Government Code; Sections 630 and 670, Vehicle Code; Section 21, Harbors and Navigation Code.

Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100837, 100870, 100872, 100880, 100905, 100907, 100910, 100915 Health and Safety Code.

**Amend Title of Article 2 as follows:**

**Article 2. ~~Certification and Amendment Process~~ Accreditation Requirements.**

**Adopt Section 64802.00 as follows:**

**Section 64802.00 Application Package.**

(a) A Complete Application Package for initial or renewal accreditation shall contain:

(1) Laboratory identifying information, which includes:

(A) Name of the laboratory;

(B) Details on the laboratory's type, location, ownership, contact information, and the regulatory agencies the laboratory reports to;

(C) Name and qualifications of Technical Manager(s), including copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;

(D) Name of Quality Manager;

(E) Signed declaration to comply with applicable ELAP statutes and regulations;

(F) Signature of the laboratory Owner, corporate officer authorized to act on behalf of the laboratory, or Owner's Agent (include documentation of authority to act on behalf of the Owner) attesting to the truthfulness of the information submitted;  
and

(G) Date of signature;

(2) A copy of the laboratory Quality Manual meeting the requirements of:

(A) 2016 TNI Standard Volume 1 – Revision 2.1, Module 2, Section 4.2.8.3 and 4.2.8.4, herein incorporated by reference; or

(B) Section 64802.05(b)(1);

(C) Subdivision (a)(2)(B), above, will become invalid three (3) years from the effective date of these regulations at which time accredited laboratories will be required to comply with subdivision (a)(2)(A), above;

(3) Signed and populated Field(s) of Accreditation tables for which accreditation is being requested;

(4) Proficiency Testing report(s) with Acceptable Scores for each Field(s) of Accreditation for which accreditation is requested in accordance with Section 64802.15;

(5) A copy of the most recently completed on-site assessment report from an Assessment Agency in accordance with Section 64802.20, including all findings and an approved Corrective Action Plan; and

(6) For aquatic toxicity testing, a current reference toxicant control chart for each method, species, and endpoint requested.

(b) A Complete Application Package for accreditation by reciprocity shall contain:

(1) Laboratory identifying information, which includes:

(A) Name of the laboratory;

(B) Details on the laboratory's type, location, ownership, contact information, and the regulatory agencies the laboratory reports to;

(C) Name and qualifications of Technical Manager(s), including copies of applicable degrees;

(D) Name of Quality Manager;

(E) Signed declaration to comply with applicable ELAP statutes and regulations;

(F) Signature of the laboratory Owner, corporate officer authorized to act on behalf of the laboratory, or Owner's Agent (include documentation of authority to act on behalf of the Owner) attesting to the truthfulness of the information submitted; and

(G) Date of signature;

(2) A copy of the laboratory Quality Manual meeting the requirements of:

(A) 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, Section 4.2.8.3 and 4.2.8.4, herein incorporated by reference; or

(B) Section 64802.05(b)(1);

(C) Subdivision (b)(2)(B), above, will become invalid three (3) years from the effective date of these regulations at which time accredited laboratories will be required to comply with subdivision (b)(2)(A), above;

(3) Signed and populated Field(s) of Accreditation tables for which accreditation is being requested;

(4) Proficiency Testing report(s) with acceptable scores for each Field(s) of Accreditation for which accreditation is requested in accordance with Section 64802.15;

(5) A copy of the most recently completed on-site assessment report, including all findings and an approved Corrective Action Plan;

(6) For aquatic toxicity testing, a current reference toxicant control chart for each method, species, and endpoint requested; and

(7) Proof of accreditation from a Primary Accreditation Body, including:

(A) Official certificate of accreditation and scope of accreditation;

(B) Official on-site assessment report and findings; and

(C) Corrective Action Plan(s) reviewed and approved by the Primary Accreditation Body.

(c) A complete amendment application package shall be submitted to ELAP in accordance with Section 64808.15.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100829, 100830, 100840, 100860.1, 100870, Health and Safety Code.

**Adopt Section 64802.05 as follows:**

**Section 64802.05. Quality Systems.**

To ensure analytical data produced by the laboratory are of known and documented quality, and sufficient to evaluate the usability of the data for State Regulatory Agency needs, a laboratory shall:

(a) Comply with quality system requirements in accordance with 2016 TNI Standard – Revision 2.1, Volume 1:

(1) Module 2, herein incorporated by reference, with the following exceptions:

(A) Module 2, Section 4.1.7.2(f) – Technical Manager Qualifications; and

(B) Module 2, Section 5.2.6 – Technical Manager Requirements;

(2) Modules 3 through 7, herein incorporated by reference, where appropriate based on laboratory operations; or

(b) Develop and implement a quality assurance program. As evidence of such a program, the laboratory shall:

(1) Develop and maintain a Quality Manual. The Quality Manual shall address the quality assurance and quality control practices to be employed by the laboratory and shall include at a minimum:

(A) The quality assurance and quality control requirements specified in the test methods for which the laboratory seeks to obtain or maintain accreditation for; and

(B) Documents, or references to documents, that contain the following elements:

(i) Laboratory organization and job descriptions;

(ii) Ethics and integrity clause;

(iii) Quality assurance objectives for measurement data;

(iv) Sampling procedures (when the laboratory performs the sampling);

(v) Procedures for sample acceptance/rejection, custody, handling, and disposal of samples;

(vi) Calibration procedures and frequency;

(vii) Analytical procedures;

(viii) Acquisition, reduction, validation and reporting of data;

(ix) Internal quality control checks;

(x) Performance and system audits;

(xi) Preventive maintenance;

(xii) Assessment of precision and accuracy;

(xiii) Corrective action; and

(xiv) Quality assurance reports;

(2) The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs:

(A) Changes to laboratory equipment or instrumentation;

(B) Changes to laboratory structure or physical arrangements; or

(C) Changes in the laboratory organization;

(3) Perform annual quality assurance audits documenting compliance with subdivision (b)(1), above, including corrective actions for any noted findings. Audit reports shall be provided to ELAP upon request; and

(4) Maintain records of the implementation of the quality assurance program. Records of the implementation of the quality assurance program shall be provided to ELAP upon request.

(c) Subdivision (b), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (a), above.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100829, 100830, 100840, 100860.1, 100865, 100870 Health and Safety Code.

**Adopt Section 64802.10 as follows:**

**Section 64802.10. Field(s) of Accreditation.**

(a) ELAP will accredit laboratories in Field(s) of Accreditation required by State Regulatory Agencies for Regulatory Purposes.

(b) Field(s) of Accreditation offered for the purpose of drinking water analyses shall include United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations parts 141.21 through 141.42, 141.66, 141.89, and Appendix A of Subpart C, or as otherwise directed by the State Water Board.

(c) Field(s) of Accreditation offered for the purpose of compliance monitoring under the Clean Water Act shall include United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations part 136, or as otherwise directed by the State Water Board or other State Regulatory Agency.

(d) Field(s) of Accreditation offered for the purpose of solid and hazardous waste material analyses shall include United States Environmental Protection Agency approved methods as prescribed in SW-846, Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, or as otherwise directed by the State Water Board or other State Regulatory Agency.

(e) ELAP publishes the lists of Field(s) of Accreditation, called Field(s) of Accreditation tables, on the ELAP website. The Field(s) of Accreditation tables are updated, as needed, by publishing a revised Field(s) of Accreditation table on the ELAP website.

Note: Authority cited: Section 100830 Health and Safety Code: Reference: Sections 100825, 100830, 100840, 100850, 100852 Health and Safety Code.

**Adopt Section 64802.15 as follows:**

**Section 64802.15. Proficiency Testing.**

(a) The Proficiency Testing requirements in this section shall not negate or supersede the Proficiency Testing requirements of other state or federal regulatory programs.

(b) When participating in a Proficiency Testing study, a laboratory shall:

(1) Comply with 2016 TNI Standard - Revision 2.1, Volume 1, Module 1, herein incorporated by reference, for each Field of Accreditation for which the laboratory is requesting accreditation, with the following exceptions:

(A) Volume 1, Module 1, Section 5.0 – Proficiency Testing Study Frequency Requirements for Accreditation; and

(B) Volume 1, Module 1, Section 8.0 – Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation; or

(2) Comply with the following Proficiency Testing requirements:

(A) Analyze Proficiency Testing samples in accordance with the laboratory's routine standard operating procedure using the same quality control, acceptance criteria, and staff as used for the analysis of routine environmental samples;

(B) Analyze Proficiency Testing samples of the same matrix as the Field(s) of Accreditation for which the laboratory holds or seeks accreditation;

(C) On or before the closing date of the study, direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP;

(D) Report in such a way that results of the Proficiency Testing study corresponds to the Field of Accreditation offered by ELAP; and

(E) Retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for Proficiency Testing samples for a minimum of five (5) years and provide them to ELAP upon request; and

(3) Not engage in the following activities:

(A) Send Proficiency Testing study samples, in which the laboratory is participating, to another laboratory for the analysis of a Field of Accreditation for which it seeks accreditation or is accredited;

(B) Knowingly receive or analyze any Proficiency Testing samples from another laboratory for which the results are to be used for accreditation;

(C) Communicate with any individual at another laboratory concerning the analysis of Proficiency Testing samples of an ongoing study;

(D) Attempt to obtain the assigned value of any portion of a Proficiency Testing study from the Proficiency Testing provider; and

(E) Request the Proficiency Testing provider to alter any portion of the laboratory's Proficiency Testing report after it was issued as final.

(c) Subdivisions (b)(2) and (b)(3), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (b)(1), above.

(d) If there are no available Proficiency Testing samples for a Field(s) of Accreditation, ELAP may require verification of quality control data as an alternative demonstration of capability.

(e) To obtain initial accreditation, within twelve (12) months prior to ELAP's receipt of the laboratory's initial application package, a laboratory shall achieve Acceptable Scores in a Proficiency Testing study for each Field of Accreditation requested in the application.

(f) To maintain accreditation, a laboratory shall achieve Acceptable Scores in a Proficiency Testing study at least once per year for each Field of Accreditation for which the laboratory holds accreditation. Acceptable Scores in Proficiency Testing studies shall be achieved:

(1) Within twelve (12) months from the accreditation date in year one of the accreditation period; and

(2) At least ninety (90) days prior to the expiration date of accreditation in year two of the accreditation period.

(g) To add or reinstate a Field of Accreditation, a laboratory shall achieve Acceptable Scores in a Proficiency Testing study for each Field of Accreditation for

which the laboratory is requesting to add and submit an amendment application in accordance with Section 64808.15.

(h) If on the first attempt, a laboratory does not achieve an acceptable score for a Field of Accreditation, then within forty-five (45) days of receipt of the “Not Acceptable” score from the Proficiency Testing provider, the laboratory shall:

(1) Notify ELAP of the “Not Acceptable” score;

(2) Document the root cause of the failure;

(3) Take corrective action;

(4) Achieve an acceptable score in a subsequent Proficiency Testing study for that Field of Accreditation;

(5) Notify ELAP of the “Acceptable” score; and

(6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

(i) If a Proficiency Testing study for a Field of Accreditation is not available within forty-five (45) days of receipt of a “Not Acceptable” result, the laboratory shall:

(1) Submit a plan to ELAP that states when the next Proficiency Testing study will be completed, and;

(2) Achieve Acceptable Scores for the Field of Accreditation when the subsequent Proficiency Testing study becomes available and submit to ELAP.

(j) If on the second attempt, a laboratory does not achieve an acceptable score for a Field of Accreditation a laboratory shall:

(1) Notify ELAP of the “Not Acceptable” result within three (3) days;

(2) Be suspended for that Field of Accreditation;

(3) Cease reporting of results for Regulatory Purposes for that corresponding Field of Accreditation;

(4) Notify affected Clients of second “Not Acceptable” Proficiency Testing result by registered mail, email with return receipt, or electronic signature document;

(5) Within thirty (30) days: investigate and document the root cause of the failure and take corrective action;

(6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

(k) To be reinstated after Suspension of a Field(s) of Accreditation, the laboratory shall:

(1) Achieve Acceptable Scores in a Proficiency Testing study for the corresponding Field(s) of Accreditation; and

(2) Submit an amendment application package, in accordance with Section 64808.15.

(l) For toxicity bioassay analyses, each laboratory shall:

(1) Achieve Acceptable Scores in a Proficiency Testing study, where available, for each Field of Accreditation for which the laboratory is requesting accreditation, in accordance with (b), above;

(2) Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint; and

(3) Plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint.

(m) For pesticide residue in food, each laboratory shall obtain Proficiency Testing samples from a Proficiency Testing provider that meets TNI standards.

(n) If a laboratory has a financial interest, familial relationship, or contractual agreement for consultation with the provider of a Proficiency Testing study, the results from that study shall not be used to meet the Proficiency Testing study requirements for accreditation.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100850, 100865, 100870, 100872 Health and Safety Code.

**Adopt Section 64802.20 as follows:**

**Section 64802.20. On-Site Assessment.**

(a) An on-site assessment, either announced or unannounced, shall be conducted by an Assessment Agency to verify the information submitted with a laboratory's application and to verify a laboratory is in compliance with:

(1) Quality system requirements, in accordance with Section 64802.05;

(2) Analytical methods used for each Field of Accreditation for which the laboratory seeks to obtain or maintain accreditation;

(3) Laboratory instrumentation, equipment, and facility requirements, in accordance with Section 64812.05; and

(4) All applicable ELAP statutes and regulations.

(b) An on-site assessment shall be conducted:

(1) For initial accreditation, no more than twelve (12) months prior to applying for accreditation;

(2) For renewal accreditation, once within the two (2) years prior to the expiration date of accreditation;

(3) For amendment accreditation, in accordance with Section 64808.15;  
and

(4) For enforcement purposes, when ELAP decides to conduct an assessment in accordance with Health and Safety Code section 100865.

(c) An on-site assessment shall be conducted by ELAP or a third-party Assessment Agency contracted by ELAP to perform on-site assessments.

(1) A laboratory requesting assessment to Field(s) of Accreditation that utilizes Sophisticated Technology shall use a third-party Assessment Agency;

(2) A third-party Assessment Agency shall be one of the following:

(A) A National Environmental Laboratory Accreditation Program (NELAP)-recognized accreditation body;

(B) A NELAP-recognized non-government accreditation body; or

(C) An agency that is recognized by the Department of Defense or Department of Energy as an accrediting body.

(3) ELAP will publish a list of approved third-party Assessment Agencies on the ELAP website.

(d) The laboratory is responsible for requesting an on-site assessment through ELAP or a third-party Assessment Agency.

(e) When a scheduled on-site assessment is performed by ELAP, a laboratory shall pay an assessment fee in accordance with Section 64802.25.

(f) When an on-site assessment is performed by a third-party Assessment Agency contracted by ELAP to perform on-site assessments, a laboratory shall pay the third-party Assessment Agency its market rate for onsite assessments.

(g) Within thirty (30) days of the on-site assessment, a laboratory shall receive an on-site assessment report. If there are findings in the on-site assessment report, a laboratory shall:

(1) Within thirty (30) days of receipt of the on-site assessment report, submit a Corrective Action Plan that contains a Root Cause Analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected.

(2) Subsection (g)(1), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to submit, within thirty (30) days of receipt of the on-site assessment report, a Corrective Action

Plan that contains a Root Cause Analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected in accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.11, 4.12, and 4.13, herein incorporated by reference.

(h) If a laboratory is notified that a Corrective Action Plan does not address the finding(s) identified, then the laboratory shall have an additional thirty (30) days from the receipt of the notification to submit a revised Corrective Action Plan. If the revised Corrective Action Plan does not demonstrate the required corrections have been made, then ELAP will take action to deny, suspend or revoke accreditation for the Field(s) of Accreditation affected by the failure to take corrective action.

(i) If a subsequent on-site assessment, either announced or unannounced, reveals that a laboratory failed to take the corrective action(s) specified in a Corrective Action Plan, ELAP will take action to deny, suspend, or revoke accreditation for the Field(s) of Accreditation affected by failure to take corrective action.

(j) If a scheduled on-site assessment is not conducted within six (6) months from the scheduled assessment date and the delay is not a result of the Assessment Agency error or procedure, ELAP may take action to deny, suspend or revoke accreditation.

(k) If a laboratory has submitted a complete renewal or amendment application package in accordance with Section 64808.05 or 64808.15, respectively, and additional time is needed by the Assessment Agency to complete an on-site assessment, then the laboratory shall be issued an interim certificate of accreditation.

(1) A laboratory that holds an interim certificate of accreditation is accredited for Field(s) of Accreditation listed on the laboratory scope of accreditation.

(2) An interim certificate is non-renewable and shall be valid until one of the following occurs:

(A) An on-site assessment has been completed and a certificate of accreditation issued;

(B) The laboratory fails to meet the requirements for accreditation in accordance with Article 2; or

(C) The expiration date on the interim certificate of accreditation is reached.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100837, 100850, 100865, 100870, 100872 Health and Safety Code.

**Repeal Section 64803 as follows:**

**~~Section 64803. Certification and Amendment.~~**

~~(a) A laboratory and its auxiliary or mobile laboratories shall be certified for a 24 month period in the Subgroups within each Field of Testing applied for when all the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation sample study sets have been received by the Department pursuant to Section 64809; and~~

~~(4) payment of the basic fee and per Field of Testing fees published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) has been made to the Department.~~

~~(b) A laboratory desiring to add or remove one or more Subgroups within a Field(s) of Testing from its current certificate shall file a written request detailing the Field(s) of Testing or Subgroup(s) to be added or removed. Additions, which shall be effective for the remainder of the certification period, shall be made, and an amended certificate issued, when all of the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation samples have been received by the Department pursuant to Section 64809; and~~

~~(4) payment for a per Field of Testing fee published by the Department pursuant to Health and Safety Code, Sections 113 and 1017(a) for each Field of Testing to be added to the certificate has been made to the Department.~~

~~(c) Whenever there is an amendment to a certificate, the certificate number and the expiration date on the amended certificate shall be the same as the original certificate.~~

~~(d) Laboratories seeking an amendment to add one or more Subgroups within a Field(s) of Testing shall not perform analyses in the additional Field(s) of Testing, or Subgroup(s) of Field(s) of Testing, until approved by the Department as evidenced by the issuance of an amended certificate.~~

~~(e) Laboratories seeking removal of one or more Subgroups within a Field(s) of Testing shall not perform analyses in the Field of Testing, or Subgroup, after the date of its written request for removal.~~

~~(f) A laboratory desiring interim certification under authority of Health and Safety Code, Section 1015(d) shall file a written request for interim certification with its application. An interim certificate shall be issued after payment of the basic and per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) for each Field of Testing applied for, completion of the requirements of either Section 64807 or 64809, and after the Department has determined that the laboratory has submitted a complete application. In cases where reciprocity agreements exist, compliance with Section 64807 shall be based on a site~~

~~visit report issued by the other government agency and conducted within 6 months prior to the request for interim certification.~~

~~(g) The Department's estimated schedule for processing a complete application for certification from the receipt of the complete application to the final decision regarding issuance or denial of a certificate is as follows:~~

~~(1) The median time is 6 months;~~

~~(2) The minimum time is 3 months;~~

~~(3) The maximum time is 12 months.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 113, 1012, 1013, 1014 and 1015, Health and Safety Code.~~

**Amend Title of Article 3 as follows:**

**Article 3. Application Process Types of Accreditation.**

**Repeal Section 64805 as follows:**

~~Section 64805. Application.~~

~~(a) All laboratories seeking certification in any Subgroup as identified in Section 64823 within Field(s) of Testing 1 through 22, as listed in Health and Safety Code, Section 1017, shall file a complete application utilizing ELAP form 001, dated January 1, 1993, and containing the following information:~~

~~(1) complete name of the laboratory; and~~

~~(2) if the laboratory is stationary, the location, by street address, or map directions (if no street address exists), city, state, zip code, and county of the laboratory and any auxiliary laboratories; and~~

~~(3) if the laboratory is owned by a holder of a waste discharge permit issued by a California Regional Water Quality Control Board, the name or number of the Regional Board issuing the permit; and~~

~~(4) mailing address, parcel or package delivery address of the laboratory and any auxiliary laboratories; and~~

~~(5) if the laboratory is a vehicle or trailer, the vehicle identification and license plate number, including state of issue, or if the laboratory is a vessel, the vessel identification number, vessel registration number, including state of issue, or if the laboratory is an aircraft, the aircraft identification number, aircraft registration number, including state of issue, of all mobile laboratories; and~~

~~(6) name, education, and experience for the person designated as the Laboratory Director; and~~

~~(7) name, education, and experience for each and every person designated as Principal Analyst; and~~

~~(8) name of a Contact Person; and~~

~~(9) phone numbers for the laboratory, fax devices, Laboratory Director, and Contact Person; and~~

~~(10) the name(s) of the Owner(s) of the laboratory. If the laboratory is owned by a corporation, the name of the officers, and stockholders owning 5% or more of the shares. If the laboratory is owned by a partnership, the name of all partners; and~~

~~(11) whether the laboratory seeks exemption from fees as allowed by Health and Safety Code, Section 1017(e). If exemption is claimed, it shall include evidences showing the laboratory to be established under the authority of Health and Safety Code, Section 1000, or that the laboratory meets the definition of a government-owned reference laboratory as established in Health and Safety Code, Section 1017(g); and~~

~~(12) the Field(s) of Testing for which the laboratory desires certification;~~

and

~~(13) a quality assurance document meeting the requirements of Section 64815; and~~

~~(14) date of completion of the application and signature by an Owner.~~

~~(b) Laboratories seeking certification of a mobile laboratory under Field of Testing 23, shall file a complete application, which shall include the following information:~~

~~(1) the Subgroup within the Field of Testing to be employed in the mobile laboratory; and~~

~~(2) the name of the Owner(s) of the stationary laboratory that operates the mobile laboratory; and~~

~~(3) name, education, and experience for the person designated as Laboratory Director for the stationary laboratory that operates the mobile laboratory; and~~

~~(4) name, education and experience for each and every person designated as Principal Analyst for the mobile laboratory; and~~

~~(5) a quality assurance program meeting the requirements of Section 64815 covering the test methods to be employed in the mobile laboratory; and~~

~~(6) the location, by street address, or map directions (if no street address exists), city, state, zip code, and county of the certified stationary laboratory under the same owner as the mobile laboratory and the Subgroups within each Field of Testing for which that stationary laboratory is certified.~~

~~(c) All applications filed with the Department shall be considered complete unless within 30 days of receipt, the Department mails to the laboratory's mailing address a notice that the application is not complete. Any noted deficiencies in a submitted application must be corrected and the corrected application returned to the Department~~

~~within ninety days from the date of the Department's notice of deficiencies or the application shall be considered null and void.~~

~~(d) An application for renewal of a certificate shall be received by the Department no later than ninety days prior to the expiration date of the certificate or it shall expire by operation of law on the stated expiration date as specified in Health and Safety Code Section 1014(a).~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Sections 1013, 1014 and 1017(e), Health and Safety Code.~~

**Repeal Section 64806 as follows:**

~~Section 64806. Certification Fees.~~

~~(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal Environmental Laboratory Accreditation Program certification:~~

~~(1) A non-refundable base or administrative fee of \$2268 payable at the time of initial and renewal application for certification and annually thereafter, and~~

~~(2) An additional non-refundable fee of \$1021 for each Field of Testing for which the laboratory has requested in its application that it be certified, payable at the time of application for an initial, amended, or renewed ELAP certification, and annually thereafter.~~

~~Note: Authority cited: Sections 100829, 100830 and 116271, Health and Safety Code. Reference: Section 100829, Health and Safety Code.~~

**Adopt Section 64808.00 as follows:**

**Section 64808.00 Initial Accreditation.**

(a) The period of accreditation for initial accreditation shall be twenty-four (24) months.

(b) To obtain initial accreditation, a laboratory shall:

(1) Submit a Complete Application Package, in accordance with Section 64802.00; and

(2) Pay the required fees in accordance with Section 64802.25.

(c) If any of the elements in Section 64802.00 are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory of the missing elements. When reviewing for completeness of an application package ELAP will only ensure each element has been submitted with the application package, and not that each element meets minimum requirements.

(1) To resume processing, a Complete Application Package shall be returned to ELAP within thirty (30) days from the date of ELAP's notification.

(2) If a Complete Application Package is not returned to ELAP within thirty (30) days of receiving notice, then the application shall be denied by ELAP.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845 Health and Safety Code.

**Adopt Section 64808.05 as follows:**

**Section 64808.05 Renewal Accreditation.**

(a) The period of accreditation following the renewal of accreditation shall be twenty-four (24) months.

(b) To renew accreditation, a laboratory shall:

(1) Submit a Complete Application Package, in accordance with Section 64802.00, ninety (90) days prior to the expiration date of the certificate of accreditation; and

(2) Pay the required fees in accordance with Section 64802.25.

(c) If any of the elements in Section 64802.00 are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory. When reviewing for completeness of an application package ELAP will only ensure each element has been submitted with the application package, and not that each element meets minimum requirements.

(1) To resume processing, a Complete Application Package shall be returned to ELAP within thirty (30) days from the date of ELAP's notification.

(2) If a Complete Application Package is not returned to ELAP within thirty (30) days, the application shall be denied by ELAP.

(d) If a laboratory submits a renewal application package after the application due date, the laboratory shall be subject to a late fee equal to 15% of the accreditation fee.

(1) ELAP will use the date a Complete Application Package is received as the submittal date.

(2) Submittal of late renewal application could result in a lapse in accreditation. If accreditation is not renewed by the expiration date on the certificate of accreditation, the laboratory shall cease all reporting of results for Regulatory Purposes and notify Clients of the lapse in accreditation by registered mail, email with return receipt or electronic signature document.

(e) If a laboratory submits a renewal application package after the expiration date on its certificate of accreditation, the laboratory shall be subject to a late fee equal to 30% of the accreditation fee.

(1) ELAP will use the date a Complete Application Package is received as the submittal date.

(2) The laboratory shall cease all reporting of results for Regulatory Purposes on the expiration date on its certificate of accreditation and notify Clients of

the lapse in accreditation by registered mail, email with return receipt, or electronic signature document.

(f) If a laboratory submits a renewal application package ninety (90) days after the expiration date on its certificate of accreditation, then accreditation shall not be renewable.

(1) ELAP will use the date a Complete Application Package is received as the submittal date.

(2) The laboratory shall cease all reporting of results for Regulatory Purposes on the expiration date of its certificate of accreditation and notify Clients of the lapse in accreditation by registered mail, email with return receipt, or electronic signature document.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845 Health and Safety Code.

**Adopt Section 64808.10 as follows:**

**Section 64808.10 Reciprocity Accreditation.**

(a) Laboratories physically located outside of the State of California shall obtain accreditation through reciprocity.

(b) For laboratories physically located outside the State of California, the environmental laboratory accreditation program of another state or federal agency shall be recognized for the purposes of reciprocity if the accreditation program requirements related to quality systems, test methods, Proficiency Testing, on-site assessments, personnel, and laboratory facilities and equipment are at least as stringent as ELAP accreditation requirements.

(c) The environmental laboratory accreditation programs of other state or federal agencies shall be recognized for reciprocity through a written agreement with ELAP.

(d) For reciprocity accreditation, the period of accreditation shall be the time remaining on the certificate of accreditation provided by the Primary Accreditation Body. If a laboratory submits a certificate of accreditation from more than one Primary Accreditation Body, then the period of accreditation will be the time remaining on the certificate of accreditation that expires first.

(e) A laboratory applying for accreditation by reciprocity shall:

(1) Submit a Complete Application Package in accordance with Section 64802.00(b); and

(2) Pay the required fees in accordance with Section 64802.25.

(f) A laboratory accredited through reciprocity may be subject to an on-site assessment. When ELAP conducts an on-site assessment for an out-of-state laboratory, the laboratory shall reimburse ELAP for all per diem and travel expenses incurred, in addition to the assessment fees in accordance with Section 64802.25.

(g) If a laboratory, accredited through reciprocity, is notified of Suspension or Revocation of its certificate of accreditation by its Primary Accreditation Body, then the laboratory shall:

(1) Cease all reporting of results for Regulatory Purposes; and

(2) Notify ELAP within ten (10) days of the notification of Suspension or Revocation.

(h) If a reciprocity agreement with the accreditation program of another state or federal agency is revoked by ELAP, any certificate of accreditation issued by ELAP to an affected laboratory shall be valid until the expiration date on the certificate of accreditation.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference Sections 100825, 100829, 100895 Health and Safety Code.

**Adopt Section 64808.15 as follows:**

**Section 64808.15 Amendment Accreditation.**

(a) When a certificate of accreditation is amended, the period of accreditation shall be the time remaining on the certificate of accreditation from the date it was amended.

(b) To amend accreditation, a laboratory shall:

(1) Submit an amendment application package;

(2) Pay the required fee in accordance with Section 64802.25.

(c) A laboratory shall submit an amendment application package for the following reasons:

(1) Change in laboratory name, except if the change in laboratory name is in connection with a sale or transfer of ownership, then the laboratory shall comply with Section 64814.05;

(2) Change in laboratory location;

(3) Addition of a satellite laboratory or mobile laboratory to the existing accreditation; or

(4) Addition or reinstatement of Field(s) of Accreditation to the laboratory's current certificate of accreditation.

(d) Amendments to a laboratory's accreditation are not accepted in the renewal application package. A separate amendment application package shall be submitted to amend accreditation.

(e) A laboratory applying for a change in laboratory name shall submit an amendment application package that includes the following:

(1) Existing name of the laboratory;

(2) Certificate number of the laboratory;

(3) Address of the laboratory;

(4) Proposed new name of the laboratory;

(5) Signature of the laboratory Owner, Owner's Agent, or officer; and

(6) Signature date.

(f) A laboratory applying for a change in laboratory location shall:

(1) Within thirty (30) days prior to the change of location, submit a relocation plan to ELAP that includes the following laboratory identifying information:

(A) Name of the laboratory;

(B) Certificate number of the laboratory;

(C) Existing address of the laboratory;

(D) Address of the new location;

(E) Description of the new location;

(F) Timeline of the change in location;

(G) Signature of the laboratory Owner, Owner's Agent, or officer;

and

(H) Signature date;

(2) During the change in location, the laboratory shall:

(A) Comply with quality system requirements at the new location, in accordance with Section 64802.05; and

(B) Cease reporting data for Regulatory Purposes at the old location once the new location is reporting data for Regulatory Purposes;

(3) Within ninety (90) days after the change of location, submit an amendment application package that includes the following:

(A) Laboratory identifying information, which includes:

(i) Name of the laboratory;

(ii) Certificate number of the laboratory;

(iii) Existing or previous address of the laboratory;

(iv) New address of the laboratory;

(v) Description of the new location;

(vi) Signature of the laboratory Owner, Owner's Agent, or officer; and

(vii) Signature date;

(B) A copy of the laboratory Quality Manual, with updates necessitated by the change of location;

(C) A copy of new or revised standard operating procedure(s) necessitated by the change of location;

(D) Proficiency Testing report(s) with Acceptable Scores for the Field(s) of Accreditation for which the laboratory is requesting accreditation, whereby analysis occurred at the new location; and

(E) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved Corrective Action Plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20, whereby the assessment occurred at the new location;

(g) A laboratory applying to add a satellite or mobile laboratory to an existing accreditation shall:

(1) Prior to applying, ensure the laboratory meets the criteria for a satellite laboratory or mobile laboratory in accordance with Sections 64810.05 and 64810.10, respectively;

(2) Submit an amendment application package that includes the following:

(A) Laboratory identifying Information including:

(i) Name of the laboratory;

(ii) Details on the laboratory's type, size, location, business entity type, contact information and ownership;

(iii) Name and qualifications of the Technical Manager(s), including copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;

(iv) Name of the Quality Manager, if applicable;

(v) Agreement to comply with applicable ELAP statutes and regulations;

(vi) Signature of the laboratory Owner, Owner's Agent, or officer; and

(vii) Signature date;

(B) Signed and populated Field(s) of Accreditation tables for which the satellite laboratory or mobile laboratory is requesting accreditation;

(C) Proficiency Testing report(s) with Acceptable Scores for each Field of Accreditation for which the satellite laboratory or mobile laboratory is requesting accreditation, whereby analysis occurred at the satellite or mobile laboratory; and

(D) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved Corrective Action Plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20, whereby the assessment occurred at the new laboratory;

(3) Pay the required fee in accordance with section 64802.25.

(h) A laboratory applying to add or reinstate Field(s) of Accreditation shall submit an amendment application package that includes the following:

(1) Laboratory identification information including:

(A) Name of the laboratory;

(B) Certificate number of the laboratory; and

(C) Address of the laboratory;

(2) Signed and populated Field(s) of Accreditation tables for which accreditation is being amended;

(3) A copy of the laboratory Quality Manual, with updates necessitated by the addition of Field(s) of Accreditation;

(4) Proficiency Testing report(s) with Acceptable Scores for each Field of Accreditation for which the laboratory is requesting to add; and

(5) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved Corrective Action Plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20.

(i) The on-site assessment requirement for an amendment accreditation package may be waived if ELAP determines the amendment to accreditation would not affect the quality of the data.

(j) A laboratory is not required to submit an amendment application to remove Field(s) of Accreditation but may request an amended certificate of accreditation to remove Field(s) of Accreditation by submitting a written request to ELAP. Once a laboratory requests an amended certificate of accreditation, the laboratory shall cease reporting results for Regulatory Purposes of all removed Field(s) of Accreditation.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845, 100850, 100870 Health and Safety Code.

**Amend Title of Article 4 as follows:**

**Article 4. Site Visits Types of Laboratories.**

**Repeal Section 64807 as follows:**

~~Section 64807. Site Visits.~~

~~(a) Site visits shall be conducted by the Department to verify information contained in a laboratory's application for certification or when a laboratory requests the addition of one or more Subgroups within a Field of Testing. During the site visit, the Department shall verify the following:~~

~~(1) the laboratory uses only the analytical test methods identified in Section 64811 for each Subgroup within a Field of Testing for which the laboratory is seeking certification;~~

~~(2) the laboratory's instrumentation and equipment meet the requirements of Section 64813;~~

~~(3) the laboratory's quality assurance and quality control procedures meet the requirements of Section 64815; and~~

~~(4) the information contained in the application.~~

~~(b) Within 30 days of completion of a site visit, the Department shall notify a laboratory, in writing, of its deficiencies, if any, in complying with the requirements of (a)(1) through (a)(4) above. No laboratory shall be issued a certificate in any Subgroup within any Field of Testing applied for unless it has corrected all deficiencies noted, and has forwarded to the Department a statement, in writing, of all corrective actions taken. The statement of corrective actions shall be received by the Department within the time frame established in the Department's notice of deficiencies. If in a subsequent site visit the Department determines that the laboratory failed to take any of the corrective action(s) specified in the laboratory's statement, citation(s) as specified under the authority of Health and Safety Code, Section 1021, may be issued.~~

~~(c) A site visit shall be conducted within 6 months from the date of receipt by the Department of a laboratory's application. If a site visit is not conducted within this time~~

~~period and the delay is not a result of Department error or procedure, certification shall be denied pursuant to Section 64803(a)(2).~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Sections 1015, 1018 and 1021, Health and Safety Code.~~

**Adopt Section 64810.00 as follows:**

**Section 64810.00 Main Laboratory.**

(a) A laboratory may apply for accreditation as a main laboratory, in accordance with Section 64808.00, if the laboratory is:

(1) Designated as the primary location; and

(2) A fixed, permanent facility, which may include fixed-in-place vehicles.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Section 100825, 100830 Health and Safety Code.

**Adopt Section 64810.05 as follows:**

**Section 64810.05 Satellite Laboratory.**

(a) A satellite laboratory is a fixed, permanent facility (which includes fixed-in-place vehicles) that operates under a single scope of accreditation with a main laboratory.

(b) A main laboratory may apply for accreditation of a satellite laboratory under a single scope of accreditation, in accordance with Section 64808.15, if the following criteria are met:

(1) The main laboratory and satellite laboratory operate under the same

Owner;

(2) The satellite laboratory operates with oversight from the main laboratory;

(3) The main laboratory and satellite laboratory are under the supervision of the same Technical Manager;

(4) The main laboratory and satellite laboratory operate under the same quality management system and Quality Manual;

(5) Reports identify which laboratory performed the analyses; and

(6) A single contact person is identified to communicate with ELAP regarding accreditation activities for the main laboratory and satellite laboratory.

(c) Satellite laboratories shall comply with proficiency testing requirements in Section 64802.15 and on-site assessments in accordance with Section 64802.20.

Note: Authority cited: Section 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100830 Health and Safety Code.

**Adopt Section 64810.10 as follows:**

**Section 64810.10 Mobile Laboratory.**

(a) A mobile laboratory is a portable, enclosed structure (such as a vehicle, vessel, aircraft, or trailer) designed and equipped with the necessary and appropriate accommodations and environmental conditions for the transportation and use of laboratory equipment to perform analyses in the Field(s) of Accreditation for which accreditation is requested.

(b) A mobile laboratory may operate under its own accreditation or operate under a single accreditation with a main laboratory.

(c) A mobile laboratory may apply for accreditation, in accordance with Section 64808.00, if the mobile laboratory operates autonomously without oversight from a main laboratory.

(d) A laboratory may apply for accreditation of a mobile laboratory under a single scope of accreditation, in accordance with Section 64808.15, if the following criteria are met:

(1) The main laboratory and mobile laboratory operate under the same Owner;

(2) The mobile laboratory operates with oversight from the main laboratory.

(3) The main laboratory and mobile laboratory are under the supervision of the same Technical Manager;

(4) The main laboratory and mobile laboratory operate under the same quality management system and Quality Manual;

(5) Reports identify which laboratory performed the analyses; and

(6) A single contact person is identified to communicate with ELAP regarding accreditation activities for the main laboratory and satellite laboratory.

(e) Mobile laboratories operating under a single scope of accreditation as a main laboratory shall comply with proficiency testing requirements in Section 64802.15 and on-site assessments in accordance with Section 64802.20.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100830 Health and Safety Code.

**Amend Title of Article 5 as follows:**

**Article 5. ~~Performance Evaluation Testing Process~~ Laboratory Personnel, Facilities and Equipment.**

**Repeal Section 64809 as follows:**

~~Section 64809. Performance Evaluation Testing.~~

~~(a) No laboratory shall be certified to perform analyses in any Subgroup of any Field(s) of Testing as identified in Section 64823 unless the laboratory has submitted results for the analysis of performance evaluation sample study set(s) (where performance evaluation sample study set(s) exist) in each Subgroup within each Field of Testing for which certification is requested, and the results for the testing of the study set are in agreement with the criteria established below:~~

~~(1) within the 99% confidence limit of the mean computed by the Department for the collection of results received for the performance evaluation sample set for the following Subgroups: detection of total coliform or fecal coliform organisms in wastewater by Multiple Tube Fermentation techniques; detection of total coliform or fecal coliform organisms in wastewater by Membrane Filter techniques; Heterotrophic Plate Count techniques; Fecal streptococci and Enterococci by Multiple Tube Fermentation techniques; Fecal streptococci and Enterococci by Membrane Filter techniques of Field of Testing 1; all Subgroups in Fields of Testing 6, 9, 10, 12, 13, 16, 17, 18, and 19;~~

~~(2) positive/negative, present/absent, above/below, or other similar discrete response when the only result possible from a test is a discrete response for the following Subgroups in Field of Testing 1: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Multiple Tube Fermentation techniques; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Membrane Filter techniques; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by use of Clark's Presence/Absence medium; detection of both total coliforms and Escherichia coli (E. coli) organisms in drinking water by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside-4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) techniques;~~

~~(3) for all Subgroups in Field of Testing 8: within the 99% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set, or within the 95th percentile of a distribution of non-normal values. The choice determined by the Department through the application of standard tests that determine the normalcy of data;~~

~~(4) within the 95% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set for the following Subgroups: alkalinity, calcium, chloride, corrosivity, hardness, magnesium, MBAS, sodium, sulfate, total filterable residue and conductivity, iron (colorimetric methods only), manganese (colorimetric methods only), and ortho phosphate in Field of Testing 2; asbestos in Field of Testing 3;~~

~~(5) within a given percentage of a known or true value for the following Subgroups: cyanide, fluoride, nitrate and nitrite in Field of Testing 2; all Subgroups in Field of Testing 3, except asbestos; all Subgroups in Fields of Testing 4, 5, 20, 21, and 22.~~

~~(b) Each performance evaluation sample study set shall state the method of evaluation that shall be utilized to score results for that performance evaluation sample study set, and which requirements identified in (a) above, or (c) below must be met by the laboratory.~~

~~(c) If a performance evaluation sample study set contains one or more analytes that may be analyzed by a single test method that the Department recognizes and certifies as a Subgroup of a Field of Testing, the results shall meet one of the following:~~

~~(1) when 6 or fewer analytes are in the performance evaluation sample study set, all analytes are within the stated acceptance limits; or~~

~~(2) when more than 6 analytes are in the performance evaluation sample study set, eighty-five point zero percent (85.0%) of the analytes are within the stated acceptance limits.~~

~~(d) If a laboratory fails to submit results for the analysis of performance evaluation sample study sets, which meet the above requirements, the laboratory may, within 30 days, request that it be given a second, successive attempt to submit such results. Failure of a laboratory to submit results for the analysis of performance evaluation sample study sets meeting the requirements of (a) or (c) within 6 months from the date of receipt by the Department of the laboratory's application for~~

~~certification, or of its request for the addition of one or more Subgroups within a Field(s) of Testing shall result in the denial of the application or request.~~

~~(e) With the exception of Field of Testing 6, a certified laboratory shall, within 12 months from the date of certification, participate in at least one performance evaluation sample study set (where performance evaluation sample study set(s) exist) for each Subgroup within each Field of Testing as identified in Section 64823 for which certification is held. If the results from the study do not meet the requirements of (a) or (c), the laboratory shall be provided a second, successive attempt to submit such results. Irrespective of whether a second, successive attempt is provided, results meeting the requirements of (a) or (c) must be submitted by a certified laboratory to the Department at least 90 days prior to the expiration of its certificate or the laboratory's certificate may be restricted under Health and Safety Code, Section 1015(c).~~

~~(f) Laboratories holding certification in any Subgroup within Field of Testing 6 shall participate in all available performance evaluation test samples provided through the Environmental Protection Agency's Environmental Monitoring and Support Laboratory, Las Vegas inter-comparison cross check and performance evaluation studies. The laboratory must successfully complete a minimum of two inter-comparison cross check studies and one performance evaluation study each annual period from the date of certification. Failure to do so may be used by the Department as grounds for restricting the laboratory's certificate under Health and Safety Code, Section 1015(c).~~

~~(g) Laboratories seeking or holding certification in any Subgroup within Field of Testing 11 are exempt from compliance with the requirements of Health and Safety Code, Section 1015(b)(1).~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Sections 1015, 1017 and 1019, Health and Safety Code.~~

**Adopt Section 64812.00 as follows:**

**Section 64812.00 Laboratory Personnel.**

(a) A laboratory shall designate a Technical Manager. Except as provided in subdivisions (b) and/or (c), below, the Technical Manager shall have at minimum:

(1) A baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical science, environmental engineering, sanitary engineering, or chemical engineering; and

(2) Three (3) years' experience in the analysis of chemical, biological, or microbiological samples in an environmental laboratory, prior to being designated Technical Manager, subject to the following allowances:

(A) A master's degree in chemistry, biochemistry, biology, microbiology, natural or physical science, environmental engineering, sanitary engineering, or chemical engineering may be substituted for one (1) year of the required experience;

(B) A doctorate in chemistry, biochemistry, biology, microbiology, natural or physical science, environmental engineering, sanitary engineering, or chemical engineering may be substituted for two (2) years of the required experience.

(b) An employee of a drinking water or wastewater treatment facility, who holds a valid CWEA Laboratory Analyst certification or CA-NV/AWWA Water Quality Analyst certification, shall be deemed to meet the qualifications of Technical Manager if the grade of certification has educational and experience requirements appropriate to the scope of analytical testing in the facility's laboratory. Table 3 below states the grades of certification and the required training or experience to obtain for each grade.

**Table 3: Analyst Certification grades and Required Training or Experience**

CA-NV AWWA	CWEA	Required Training or Experience
I	I	Microbiological Methods Solids Methods Biochemical Oxygen Demand (BOD)Methods Carbonaceous BOD Methods

CA-NV AWWA	CWEA	Required Training or Experience
II	II	Titrimetric Methods Methods using Specific Ion Electrode Technologies Colorimetric Methods
III	III	Methods using Ion Chromatography Methods using Flame Atomic Absorption Methods using Graphite Furnace Atomic Absorption
IV	IV	Methods using Gas or Liquid Chromatography Technologies Methods using Inductively Coupled Plasma Technologies

(c) The following shall be exempt from meeting the requirements in subdivisions (a) and (b), above:

(1) An individual who has continuously held the position of Technical Manager at an environmental testing laboratory since the laboratory was first accredited, provided that the accreditation date was on or before December 31, 1994; and

(2) A director of a public health laboratory, pursuant to Health and Safety Code sections 101150 and 101160.

(d) The Technical Manager, and/or their designee, shall:

(1) Comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Sections 4.1.7.2, herein incorporated by reference (with the exception of part [f]); or

(2) Be responsible for:

(A) All analytical and operational activities of the laboratory, including activities of satellite or mobile laboratories under the same certificate of accreditation;

(B) Supervision of all personnel employed by the laboratory, including personnel assigned to work in satellite or mobile laboratories under the same certificate of accreditation; and

(C) The accuracy and quality of all data reported by the laboratory, including data from satellite or mobile laboratories under the same certificate of accreditation.

(e) Subdivision (d)(2), above, will become invalid three (3) years from the effective date of these regulations, and laboratories will be required comply with subdivision (d)(1), above.

(f) If a Technical Manager is absent for a period of time exceeding:

(1) Fifteen (15) consecutive days, a person meeting the qualifications of the Technical Manager shall be designated to serve as a temporary Technical Manager; or

(2) Thirty-five (35) consecutive days, ELAP shall be notified in writing.

(g) Three (3) years from the effective date of these regulations, a laboratory shall designate a Quality Manager. The Quality Manager, and/or their designee, shall comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.1.5(i), 4.1.7.1, 4.2.6, 4.2.8.2, and 4.14.1, herein incorporated by reference.

(h) A laboratory shall designate a Principal Analyst(s) to be a user of Sophisticated Technology, defined in Section 64801.00(v), or a supervisor of the users of Sophisticated Technology. The Principal Analyst shall:

(1) Possess at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical sciences, environmental engineering, sanitary engineering, or chemical engineering; or

(2) Possess a certificate of completion in a course taught by the manufacturer of the Sophisticated Technology being used or supervised by the Principal Analyst; and

(3) Have at least six months experience in the operation of Sophisticated Technology in the analysis of environmental samples prior to obtaining the position of Principal Analyst.

(i) Subdivision (h), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to meet 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 5.2, herein incorporated by reference (excluding 5.2.6).

(i) Sophisticated Technology in the laboratory shall be operated by either the Technical Manager, Principal Analyst, or other personnel designated by the Technical Manager.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845 Health and Safety Code.

**Adopt Section 64812.05 as follows:**

**Section 64812.05 Laboratory Facilities and Equipment.**

(a) A laboratory facility shall:

(1) Comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Sections 5.3, 5.5, and 5.6, herein incorporated by reference; or

(2) Be arranged and operated so that:

(A) Utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Field(s) of Accreditation for which the laboratory is accredited;

(B) Ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond established quality control limits as specified in the approved test methods or in the laboratory's Quality Manual;

(C) The design, arrangement, housekeeping, and operation of the laboratory minimizes the potential for sample contamination;

(D) Each piece of laboratory equipment meets all operational, quality assurance, quality control, and design criteria established in the approved method(s) employed by the laboratory;

(E) Each piece of laboratory equipment is operated and maintained by the laboratory as specified in the Quality Manual and standard operating procedures; and

(F) Records are kept of all operational and maintenance activities associated with the operation of laboratory equipment.

(b) Subdivision (a)(2), above, will become invalid three (3) years from the effective date of these regulations, and laboratories will be required to comply with subdivision (a)(1), above.

(c) A laboratory shall store and handle hazardous materials in accordance with the California Code of Regulations, Title 8, Division 1, Chapter 4, Subchapter 7, General Industry Safety Orders.

(d) A laboratory shall dispose of chemical wastes and maintain records of disposal in accordance with Health and Safety Code section 25200.3.1 and California Code of Regulations, Title 22, Division 4.5, Chapter 12, Standards Applicable to Generators of Hazardous Waste.

(e) When there is a change of Sophisticated Technology the laboratory shall:

(1) Update the Quality Manual necessitated by the change of Sophisticated Technology;

(2) Update or create standard operating procedure(s) necessitated by the change of Sophisticated Technology;

(3) Submit an amendment application package in accordance with 64808.15(g), if the Sophisticated Technology is a new technology to the laboratory; and

(4) Retain all records necessary to determine compliance with this subdivision and provide these records to ELAP upon request.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100830 Health and Safety Code.

**Amend Title of Article 6 as follows:**

**Article 6. Required Test Methods Notification, Reporting, Records Retention, Change of Technical Manager or Ownership, and Trade Secrets.**

**Repeal Section 64811 as follows:**

~~Section 64811. Test Methods.~~

~~(a) Laboratories certified for any Subgroup within Fields of Testing 1 through 6, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 141 as amended July 17, 1992, 57 Federal Register 31776.~~

~~(b) Laboratories certified for any Subgroup within Fields of Testing 9 through 14, as identified in Section 64823, shall employ those methods found in Article 5, Section 66260.11, Title 22, California Code of Regulations.~~

~~(c) Laboratories certified for any Subgroup within Fields of Testing 8 or 16 through 19, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 136, amended September 11, 1992, 57 Federal Register 41830, or methods stated in any permit issued by a California Regional Water Quality Control Board. If no method is stated in the permit and there is no method cited for the substance in Part 136, the laboratory is to seek approval for the use of the method from the Regional Board issuing the permit.~~

~~(d) Laboratories certified for any Subgroup within Fields of Testing 20, 21 or 22, as identified in Section 64823, shall develop and employ analytical confirmation procedures for the verification of pesticide identification and quantification.~~

~~(e) Laboratories certified in any Subgroup within Field of Testing 7, as identified in Section 64823, shall employ those methods found in either "Recommended Procedures for the Examination of Sea Water and Shellfish", 4th edition, 1970, American Public Health Association (APHA); or "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th edition, 1984, AOAC, Arlington, Virginia. Laboratories certified in any Subgroup within Filed of Testing 15, as identified in Section 64823, shall employ methods which were submitted to the Department at time of application for certification, or at time of request to add a Subgroup within a Field of Testing and which have been approved by the Department for use in the laboratory.~~

~~(f) Laboratories may substitute alternate test methods for those allowed by (a) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process, or shall obtain a waiver from the Environmental Laboratory Accreditation Program (ELAP), prior to implementing any substitution. ELAP may grant a waiver when a State Maximum Contaminant Level (MCL) is more stringent than a federal MCL or no State MCL exists and when ELAP determines that the test method the laboratory proposes to use is one for which that laboratory was previously ELAP certified. A waiver shall be valid until a new State MCL is adopted for the analyte being detected by the method.~~

~~(g) Laboratories may substitute alternate test methods for those allowed by (b) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the California Environmental Protection Agency, Hazardous Materials Laboratory, Berkeley, California prior to implementing any substitutions.~~

~~(h) Laboratories may substitute alternate test methods for those allowed by (c) above. If such substitution is desired, the laboratory shall obtain written approval for the~~

~~alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process prior to implementing any substitution.~~

~~(i) Laboratories seeking certification for the subgroups consisting of fecal coliform or Escherichia coli (E. coli) organism technics, must also obtain, or hold, certification for the subgroups consisting of the same technic for total coliform organisms.~~

~~(j) To gain certification for individual radioactive elements or isotopes, except for uranium by fluorimetric technics, a laboratory shall obtain certification for gross alpha and beta radiation testing.~~

~~(k) A laboratory may seek certification, or hold certification for Field of Testing 11 without seeking or holding certification in Fields of Testing 10, 12, or 13. However, the laboratory shall submit all resulting preparations from the use of any of the subgroup members of Field of Testing 11 to a laboratory certified for Fields of Testing 10, 12, or 13.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Sections 1012, 1017 and 28503, Health and Safety Code; Section 12901, Title 22, California Code of Regulations; Appendices I, II and III of Article 5 (commencing with Section 66261.100), Title 22, California Code of Regulations.~~

**Adopt Section 64814.00 as follows:**

**Section 64814.00 Notification, Reporting, and Control of Records.**

(a) State Regulatory Agencies and federal agencies to whom data is reported may have notification, reporting, and record retention requirements that are in addition to requirements here, and it is the responsibility of the laboratories to know those additional regulatory requirements.

(b) If an analytical result warrants a Client notification, the notification shall occur after the Technical Manager or designee, set forth in the laboratory's Quality Manual, has approved of the result.

(c) A laboratory accredited to perform analyses on drinking water samples shall notify a water supplier's designated contact person:

(1) Immediately within 24 hours, when the following results are confirmed:

(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli);

(B) A bacterial sample result is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b);

(C) A nitrate sample result exceeds the maximum contaminant level; or

(D) A chlorite sample result collected at the entry point of a water distribution system exceeds the maximum contaminant level.

(2) Immediately within 48 hours, when the following results are confirmed:

(A) A perchlorate sample result exceeds the maximum contaminant level;

(B) A chlorine dioxide sample result exceeds the maximum residual disinfectant level; or

(C) A chlorite sample result exceeds the maximum contaminant level.

(d) If a laboratory is unable to make direct contact with a water supplier's designated contact person within 24 hours in accordance with subdivision (c)(1) above, or within 48 hours in accordance with subdivision (c)(2) above, the laboratory shall immediately notify the State Water Board. If requested by the State Water Board, the

laboratory shall provide a record of the time and method of attempts to contact the water supplier.

(e) If a water supplier is requesting that the State Water Board invalidate bacteriological sample(s) due to laboratory accident or error, as described in Title 22, California Code of Regulations, Section 64425(a)(2), the laboratory shall provide the water supplier with the following:

(1) A letter from the laboratory Technical Manager to the water supplier confirming the laboratory accident or error and agreeing to the invalidation request;

(2) Complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, and date and time of analysis for the sample(s) in question;

(3) Complete description of the error alleged to have invalidated the result(s);

(4) Copies of all analytical, operational, and quality assurance records pertaining to the incident in question;

(5) Any observations noted by the laboratory personnel when receiving or analyzing the sample(s) in question; and

(6) A Corrective Action Plan that contains a Root Cause Analysis of the laboratory accident or error, the corrective actions that will take place, and the date the finding(s) will be corrected.

(f) When a laboratory subcontracts work:

(1) The subcontracting laboratory shall comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.5, herein incorporated by reference; or

(2) The subcontracting laboratory shall comply with the following requirements:

(A) The subcontracting laboratory shall inform the customer(s) of arrangement with subcontractor(s);

(B) The subcontracting laboratory shall maintain a register of all subcontractors that are used for analytical testing;

(C) The subcontractor shall be accredited by ELAP in the Field(s) of Accreditation for analyses being performed for Regulatory Purposes;

(D) The subcontracting laboratory shall include the original of any report(s) prepared by the subcontractor; and

(E) The subcontracting laboratory shall provide the required notification in accordance with subdivision (c), above, unless there is an arrangement in writing that the subcontractor will provide the required notification.

(g) Subsection (f)(2), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (f)(1), above.

(h) A laboratory shall report to Clients:

(1) In accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 5.10, herein incorporated by reference; or

(2) In accordance with the request for analysis, the full and complete results of all requested contaminants and pollutants from the analyses of the sample or components thereof.

(i) Subsection (h)(2), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (h)(1), above.

(j) A laboratory performing bacteriological analyses on drinking water samples shall submit a bacterial monitoring report with bacteriological results to the State Water

Board in accordance with Title 22, California Code of Regulations, Section 64423.1(c)(2) and (c)(3).

(k) A laboratory performing chemical, radiological, and microbiological analyses on drinking water samples in accordance with Title 22, California Code of Regulations, Division 4, Chapter 15, Domestic Water Quality and Monitoring, shall report analytical results to the State Water Board by the 10th day of the month following the month in which the analyses were completed. The results for chemical and radiological analyses shall be reported electronically using subdivision (k)(1) and the results for microbiological analyses may only be mailed or emailed to the State Water Board. Once the State Water Board notifies the laboratory that method (k)(2) is to be used for chemical, radiological, or microbiological analyses, the laboratory will have three (3) months from the date of notification to fully implement the reporting under that subdivision.

(1) Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001; or

(2) The California Laboratory Intake Portal (CLIP) using the EQEDD CASWRCB DDW data format with quality control elements related to individual sample results in PDF or electronic format.

(l) A laboratory performing chemical analyses on drinking water samples in accordance with Title 22, California Code of Regulations, Division 4, Chapter 15.5, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors, and Chapter 17.5, Lead and Copper, or other required monitoring shall report analytical results directly to the State Water Board by the 10th day of the month following the month in which the analyses were completed. If the State Water Board is unable to accept results for these specific analytes electronically as set forth in subdivision (k), above, the results shall be submitted by hard copy or as otherwise directed by the State Water Board.

(m) A laboratory accredited for the analysis of pesticide residue in food shall verify the identity and concentration of a pesticide residue before reporting the results.

(n) A laboratory shall establish and maintain a system to control records:

(1) In accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.13, herein incorporated by reference; or

(2) That allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts. Records shall be retained for a minimum of five (5) years from generation of the last entry in the records.

(o) Subsection (n)(2), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (n)(1), above.

Note: Authority cited: Sections 100827 Health & Safety Code; Reference: Sections 100827, 100886, 116385 Health and Safety Code.

**Adopt Section 64814.05 as follows:**

**Section 64814.05 Notification of Change of Technical Manager, Quality Manager or Ownership.**

(a) When there is a change of Technical Manager and/or Quality Manager, the laboratory shall, within thirty (30) days, submit notification to ELAP that includes:

(1) Name of the laboratory;

(2) Certificate number of the laboratory;

(3) Address of the laboratory;

(4) Name(s) of existing or previous Technical Manager and/or Quality Manager;

(5) Name(s) of new Technical Manager and/or Quality Manager;

(6) Qualifications of new Technical Manager in accordance with Section 64812.00;

(7) Copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;

(8) Signature of the laboratory Owner, corporate officer authorized to act on behalf of the laboratory, or Owner's Agent (including authority to act on behalf of the Owner) attesting to the truthfulness of the information submitted; and

(9) Signature date.

(b) When the ownership of a laboratory is changed or transferred, the new Owner may request to operate under the laboratory's existing ELAP certificate of accreditation as stated in Health and Safety Code section 100845, subdivisions (b) and (c):

(1) To request to operate under the laboratory's existing ELAP certificate of accreditation, the new Owner shall, within thirty (30) days after the effective date of ownership change, submit a written request to ELAP and pay the fees in accordance with Section 64802.25. The written request shall include:

(A) Name(s) of the new Owner(s) and the Owner(s) designee, if applicable;

(B) Effective date of the change in ownership;

(C) Name(s) and qualifications of current Technical Manager;

(D) Name of current Quality Manager;

(E) Statement that the new Owner will operate pursuant to the laboratory's existing Quality Manual. If changes to the laboratory are made that may

adversely affect the quality of the analyses in Field(s) of Accreditation, the new Owner shall submit:

(i) An updated Quality Manual; and

(ii) Proficiency Testing report(s) with Acceptable Scores for each Field of Accreditation affected by the change in ownership;

(F) Statement that the laboratory will remain in the existing location;

(G) Statement that the new Owner has retained more than half of laboratory personnel upon assuming ownership;

(H) Statement that the new Owner will retain all records and data from analyses performed under the previous ownership for a minimum of five (5) years;

(I) Statement that the new Owner will comply with applicable laws and regulations;

(J) Signature of the new Owner, corporate officer authorized to act on behalf of the Owner, or Owner's Agent (including documentation of authority to act on behalf of the Owner) attesting to the truthfulness of the information submitted; and

(K) Signature date.

(2) ELAP may conduct an on-site assessment in response to a change in ownership. If an on-site assessment is conducted, the laboratory shall comply with requirements in accordance with Section 64802.20.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100845, 100865 Health and Safety Code.

**Adopt Section 64814.10 as follows:**

**Section 64814.10 Trade Secrets.**

(a) A laboratory shall notify ELAP if information provided to ELAP is designated as a Trade Secret. ELAP shall not release such information unless:

(1) The release is authorized under state or federal law; and

(2) ELAP has notified the laboratory of the impending release. Such notification shall be sent at least ten (10) days prior to releasing any information designated as a Trade Secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released.

Note: Authority cited Sections 100829, 100830 Health and Safety Code; Reference: Section 100825, 100840 Health and Safety Code.

**Amend Title of Article 7 as follows:**

**Article 7. Laboratory and Equipment Reasons for Denial, Citation, Suspension, or Revocation.**

**Repeal Section 64813 as follows:**

~~Section 64813. Laboratory and Equipment.~~

~~(a) A laboratory shall be arranged and operated so that:~~

~~(1) utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Subgroup within each Field(s) of Testing for which the laboratory is certified;~~

~~(2) ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond establish quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual;~~

~~(3) the design, arrangement, and operation of the laboratory minimizes the potential for sample contamination;~~

~~(4) the storage and handling of hazardous materials in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders, Department of Industrial Relations; and~~

~~(5) the disposal of chemical wastes is in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Wastes, State of California, Department of Health Services.~~

~~(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory.~~

~~(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory as required by the manufacturer's maintenance instructions for the equipment.~~

~~(d) Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Section 1012, Health and Safety Code; California Code of Regulations, Title 8; and Title 22, Division 4, Chapter 30, California Code of Regulations.~~

**Adopt Section 64816.00 as follows:**

**Section 64816.00 Denial of Accreditation.**

(a) Reasons for denying a laboratory's application for accreditation may include:

(1) A laboratory fails to submit a Complete Application Package in accordance with Section 64802.00;

(2) A laboratory fails to implement a quality system in accordance with Section 64802.05;

(3) A laboratory fails to comply with the analytical method(s) listed on the laboratory's application for accreditation;

(4) A laboratory fails to analyze Proficiency Testing samples or report Acceptable Scores in accordance with Section 64802.15;

(5) A laboratory submits, as its own, Proficiency Testing sample results generated by another laboratory;

(6) A laboratory fails to complete a required on-site assessment in accordance with Section 64802.20;

(7) A laboratory fails to respond to an on-site assessment report with a Corrective Action Plan in accordance with Section 64802.20;

(8) A laboratory fails to implement the corrective actions detailed in the Corrective Action Plan within the required timeframe in accordance with Section 64802.20;

(9) A laboratory fails to pay fees in accordance with Section 64802.25;

(10) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;

(11) A laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;

(12) A laboratory knowingly makes any false statement or representation pertinent to receiving accreditation;

(13) A laboratory knowingly makes any false statement or representation in an application, record, or other document; and/or

(14) The laboratory fails to comply with any other provision of these regulations.

(b) A laboratory denied accreditation may petition for reconsideration pursuant to Health and Safety Code section 100855.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100850, 100855, 100865, 100870 Health and Safety Code.

**Adopt Section 64816.05 as follows:**

**Section 64816.05 Issuance of a Citation.**

(a) Reasons for issuing a Citation may include:

(1) A laboratory fails to maintain a quality system in accordance with Section 64802.05;

(2) A laboratory fails to comply with the analytical method(s) listed on the laboratory's certificate of accreditation;

(3) A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;

(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;

(5) A laboratory fails to respond to an on-site assessment report with a Corrective Action Plan in accordance with Section 64802.20;

(6) A laboratory fails to implement the corrective actions detailed in the Corrective Action Plan within the required timeframe in accordance with Section 64802.20;

(7) A laboratory fails to pay fees in accordance with Section 64802.25;

(8) A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15(d)(e) and (f);

(9) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;

(10) A laboratory makes consistent errors in analyses or erroneous reporting;

(11) A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;

(12) A laboratory knowingly makes any false statement or representation in an application, record, or other document;

(13) A laboratory fails to notify ELAP of a change in ownership; and/or

(14) A laboratory fails to comply with any other provision of these regulations.

(b) A laboratory that receives a Citation may petition for reconsideration pursuant to Health and Safety Code section 100880(f).

Note: Authority cited: Section 100830 Health and Safety Code; Reference: Section 100880 Health and Safety Code.

**Adopt Section 64816.10 as follows:**

**Section 64816.10 Suspension or Revocation of Accreditation.**

(a) Reasons for suspending or revoking accreditation may include:

(1) A laboratory fails to maintain a quality system in accordance with Section 64802.05;

(2) A laboratory fails to comply with the analytical method(s) listed on the laboratory's certificate of accreditation;

(3) A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;

(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;

(5) A laboratory fails to respond to an on-site assessment report with a Corrective Action Plan in accordance with Section 64802.20;

(6) A laboratory fails to implement the corrective actions detailed in the Corrective Action Plan within the required timeframe in accordance with Section 64802.20;

(7) If, during an on-site assessment, ELAP determines that Suspension is necessary to protect public interest, safety or welfare;

(8) A laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;

(9) A laboratory fails to pay fees in accordance with Section 64802.25;

(10) A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15(d), (e), and (f);

(11) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;

(12) A laboratory makes consistent errors in analyses or erroneous reporting;

(13) A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;

(14) A laboratory knowingly makes any false statement or representation in an application, record, or other document;

(15) A laboratory fails to notify ELAP of a change in ownership; and/or

(16) A laboratory fails to comply with any other provision of these regulations.

(b) A laboratory issued a notice of Suspension or Revocation may request a hearing within twenty days of notice pursuant to Health and Safety Code Sections 100910 and 100915.

(c) If a laboratory's accreditation for a Field(s) of Accreditation is suspended, the laboratory shall:

(1) Cease all reporting of results for Regulatory Purposes for the Field(s) of Accreditation that were suspended; and

(2) Notify all Clients of the Suspension status within three (3) days of receiving notice of Suspension from ELAP. Notification shall be made by registered mail, email with return receipt, or electronic signature document.

(d) To reinstate a suspended Field(s) of Accreditation, a laboratory shall submit an amendment application in accordance with Section 64808.15.

(e) If a laboratory's accreditation has been revoked, the laboratory shall:

(1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, or materials that contain reference to their past accreditation status;

(2) Return its certificate of accreditation to ELAP;

(3) Cease all reporting of results for Regulatory Purposes;

(4) Notify all Clients of the Revocation status within three (3) days of receiving notice of Revocation from ELAP. Notification shall be made by registered mail, email with return receipt, or electronic signature document;

(5) Provide ELAP with a list of Clients affected by the Revocation; and

(6) Discontinue use of subcontracting agreements for Regulatory Purposes with laboratories within seven (7) days of receiving notice of Revocation from ELAP.

(f) To obtain accreditation after Revocation, the laboratory shall apply for initial accreditation, in accordance with Section 64808.00, as if it were a new laboratory.

Note: Authority cited: Section 100830 Health and Safety Code; Reference: Section 100905, 100910, 100915 Health and Safety Code.

**Repeal Article 8 as follows:**

**Article 8. ~~Quality Assurance Documents.~~**

~~Section 64815 Quality Assurance.~~

~~(a) Each laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality assurance program manual.~~

~~(b) The quality assurance program manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.~~

~~(c) The Laboratory Director shall review, and amend if necessary, the quality assurance program and quality assurance program manual at least annually. The Laboratory Director shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.~~

~~(d) A laboratory shall maintain records of the implementation of its quality assurance program, and provide those records upon request of the Department. Records shall be maintained for a minimum of three years.~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Section 1012, Health and Safety Code.~~

**Repeal Article 9 as follows:**

**~~Article 9. Laboratory Personnel.~~**

~~Section 64817. Laboratory Personnel.~~

~~(a) Each laboratory shall designate a Laboratory Director. Except as provided in (b) below, no person shall be designated as a Laboratory Director unless he or she meets the following educational and experience requirements.~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science.~~

~~(2) Has at least three years experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples. The experience requirement shall be satisfied from relevant work experience prior to the person having obtained the position of Laboratory Director. A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public hearing engineering, natural or physical science may be substituted for one year of the required experience. A doctorate in chemistry, biochemistry, environmental, sanitary or public hearing engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.~~

~~(b) Laboratory Directors of utility-owned water or wastewater treatment plant laboratories performing any of the analyses required under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Laboratory Director by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

Fields of Testing	Minimum Certificate Grade Required
1, 2 [FNa1] and 16 [FNaa1]	I
1, 2, 8 and 16	II
3, 5, 17 and 19 plus those allowed for a grade II	III
4, 6, and 18 plus those allowed for a grade III	IV

~~[FNa1] Limited to testing for: alkalinity, chloride, hardness, total filterable residue, and conductivity.~~

~~[FNa2] Limited to testing for: acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, nonfilterable residue, settleable residue, volatile residue, specific conductance, and turbidity.~~

~~(c) All Laboratory Directors of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (a) or (b) above.~~

~~(d) A Laboratory Director shall be responsible for:~~

~~(1) all analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities; and~~

~~(2) supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities, and those persons designated as Principle Analysts; and~~

~~(3) the accuracy and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.~~

~~(e) If, for any reason, a Laboratory Director leaves and is not replaced within 15 days by a person meeting the requirements specified in (a) or (b), whichever applies, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies the Department, pursuant to Section 1014(d) of the Health and Safety Code, describing the qualifications of the temporary director and receives written confirmation from the Department. An~~

~~additional extension of no more than ninety days beyond the original 90-day period may be granted by the Department, provided the laboratory can document that its good faith efforts to recruit a qualified director were unsuccessful for reason beyond its control.~~

~~(f) A Laboratory Director shall assume the position of, or shall designate another person as Principal Analyst whenever there is use of a sophisticated laboratory instrument as defined in Section 64801(k). No person shall be a Principal Analyst for a laboratory unless he or she is:~~

- ~~(1) the user of the sophisticated laboratory instrument; or~~
- ~~(2) the supervisor of the users of the sophisticated laboratory instrument.~~

~~(g) Except as provided in (h) below, no person shall be a Principal Analyst unless he or she meets the following educational and experience requirements.~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science; or~~

~~(2) Possesses a certification of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used or supervised by the Principal Analyst; and~~

~~(3) Has at least six months experience in the operation of a sophisticated laboratory instrument in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples, or food. This experience requirement must be satisfied from experience gained prior to obtaining the position of Principal Analyst.~~

~~(h) Principal Analysts of utility-owned water or wastewater treatment plant laboratories performing any analyses under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Principal Analyst by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum~~

~~grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

<del>Minimum Certificate</del>	<del>Fields of Testing</del>	<del>Grade Required</del>
<del>1, 2 and 16</del>	<del>I</del>	
<del>8 plus those allowed for a Grade 1</del>	<del>II</del>	
<del>3, 5, 17 and 19 plus those allowed for a grade II</del>	<del>III</del>	
<del>4, 6, and 18 plus those allowed for a grade III</del>	<del>IV</del>	

~~(i) All Principal Analysts of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (g) or (h) above.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Section 1012, Health and Safety Code.~~

**Repeal Article 10 as follows:**

**~~Article 10. Notification and Reporting.~~**

~~Section 64819. Notification and Reporting.~~

~~(a) Laboratories certified for Field of Testing 1, 2, 3, 4, 5, or 6 shall conform to the following reporting and notification requirements.~~

~~(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.~~

~~(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:~~

~~(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.~~

~~(B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).~~

~~(C) A nitrate sample exceeds the MCL.~~

~~(3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraphs (2)(A) or (C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.~~

~~(4) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001, by the 10th day of the month following the month in which the analyses were completed.~~

~~(5) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:~~

~~(A) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;~~

~~(B) complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;~~

~~(C) complete description of the error alleged to have invalidated the result(s);~~

~~(D) copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and~~

~~(E) any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.~~

~~(b) Laboratories certified for Fields of Testing 20, 21, or 22 shall verify the identity and quantity of a pesticide residue before reporting the results. The confirmation procedures must conform to those in Section 64811(d) of this Chapter.~~

~~(c) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) prepared by all other laboratories who are party to the agreement.~~

~~Note: Authority cited: Sections 100275, 100830, 100835 and 116375, Health and Safety Code. Reference: Sections 100825(b) and 100835, Health and Safety Code.~~

**Repeal Article 11 as follows:**

**~~Article 11. Reciprocity Agreements.~~**

~~Section 64821. Reciprocity Agreements.~~

~~(a) Another State's, or a United States agency's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if the program requires:~~

~~(1) periodic analyses of performance evaluation samples by the participating laboratories with the frequency of submittal, the method of evaluation, and the established acceptance limits at least equal to those established in Section 64809 of this Chapter;~~

~~(2) on-site evaluation of participating laboratories during which the laboratory is reviewed under criteria at least equal to that established in Section 64807 of this Chapter;~~

~~(3) standards for quality assurance, laboratory facilities, test methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Sections 64811, 64813, 64815, and 64817 of this Chapter.~~

~~(b) Where reciprocity exists, each laboratory seeking California certification shall submit:~~

~~(1) an application pursuant to Section 64805(a) of this Chapter;~~

~~(2) copies of the results evaluated, or scored, from the last performance evaluation sample testing conducted by the laboratory for the other program;~~

~~(3) copies of the last on-site evaluation report prepared by the other program and the laboratory's response to any deficiencies noted;~~

~~(4) all applicable fees pursuant to Health and Safety Code, Section 1017(a); and~~

~~(5) a copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other agency.~~

~~(c) When a reciprocity agreement exists between the Department and another State, only those laboratories that reside within the boundaries of the other State shall be eligible for certification through reciprocity.~~

~~(d) If a reciprocity agreement with another State, or U.S. government agency is revoked, all certificates issued by the Department to all affected laboratories shall remain valid until the stated expiration date.~~

~~(e) No fees are waived where reciprocity exists.~~

~~(f) A laboratory certified under reciprocity may be visited or issued performance evaluation samples by the Department for the purposes of addressing questions or concerns on quality of results raised by any California government agency who has received a report from the laboratory. Applicable performance evaluation sample costs,~~

~~pursuant to Section 1017(f) or travel costs pursuant to Section 1017(b) of the Health and Safety Code shall be paid.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Sections 1011 and 1017, Health and Safety Code.~~

**Repeal Article 12 as follows:**

**~~Article 12. Subgroups for Fields of Testing~~**

~~Section 64823. Fields of Testing.~~

~~(a) Field of Testing 1 consists of those methods whose purpose is to detect the presence of microorganisms in the determination of drinking water or wastewater quality and encompasses the following Subgroups: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Membrane Filter technics; Heterotrophic Plate Count technics; detection of both total coliforms and Escherichia coli (E. coli) organisms by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside-4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by use of Clark's Presence/Absence medium; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics, Fecal streptococci and Enterococci by Membrane Filter technics; detection of total coliforms and fecal coliforms other than for drinking water or wastewater quality.~~

~~(b) Field of Testing 2 consists of those analytes or methods whose purpose is to detect the presence of inorganic substances in the determination of drinking water quality and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technic; and encompasses the following Subgroups: alkalinity; calcium (titrimetric technics); chloride; corrosivity; fluoride; hardness (direct determination); magnesium (titrimetric technics); methylene blue active substances (MBAS); nitrate; nitrite; sodium (flame emission technics); sulfate; total~~

~~filterable residue and conductivity; iron; manganese; orthophosphate; silica; cyanide; potassium (flame emission technics).~~

~~(c) Field of Testing 3 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of drinking water quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: arsenic; barium; cadmium; total chromium; copper; iron; lead; manganese; mercury; selenium; silver; zinc; aluminum; asbestos; antimony; beryllium; nickel; thallium; calcium; magnesium; sodium; potassium.~~

~~(d) Field of Testing 4 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 524.2 for volatile organics; EPA method 501.3 for trihalomethanes; EPA method 525 for acid and base/neutral compounds; EPA method 513 for dioxins; EPA method 1613 for dioxins.~~

~~(e) Field of Testing 5 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 501.1 for trihalomethanes; EPA method 501.2 for trihalomethanes; EPA method 510 for total trihalomethanes; EPA method 508 for chlorinated pesticides; EPA method 515.1 for chlorophenoxy herbicides; EPA method 502.1 for halogenated volatiles; EPA method 503.1 for aromatic volatiles; EPA method 502.2 for both halogenated and aromatic volatiles; EPA method 504 for EDB and DBCP; EPA method 505 for chlorinated pesticides and polychlorinated biphenyls; EPA method 507 for the haloacids; EPA method 531.1 for carbamates; EPA method 547 for glyphosate; EPA method 506 for adipates and phthalates; EPA method 508A for total polychlorinated biphenyls; EPA method 548 for endosulfan; EPA method 549 for diquat and paraquat; EPA method 550 for polycyclic aromatic~~

hydrocarbons; EPA method 550.1 for polycyclic aromatic hydrocarbons; EPA method 551 for chlorination disinfection byproducts; EPA method 552 for haloacetic acids.

(f) Field of Testing 6 consists of those methods whose purpose is to detect the presence of radioactive substances in drinking water, wastewater, or hazardous wastes; and encompasses the following Subgroups: gross alpha and beta radiation; total radium; radium 226; uranium; radon 222; radioactive cesium; iodine 131; radioactive strontium; tritium; gamma emitting isotopes; gross alpha by coprecipitation; radium 228; radioactive iodine; gross alpha and beta radiation in hazardous wastes; alpha emitting radium isotopes in hazardous wastes; radium 228 in hazardous wastes.

(g) Field of Testing 7 consists of those methods whose purpose is to detect the presence of microbial contamination or toxins in the determination of shellfish meat quality and encompasses the following Subgroups: shellfish meat microbiology; paralytic shellfish poison (PSP) and other marine biotoxins; microbiology of shellfish growing waters.

(h) Field of Testing 8 consists of those methods whose purpose is to detect the presence of toxins in the determination of wastewater quality, or in hazardous wastes and encompasses the following Subgroups: hazardous waste testing pursuant to Title 22, California Code of Regulations, Section 66261.24(a)(6); wastewater testing according to Kopperdahl (1976) using freshwater fish; wastewater testing according to EPA/600/4-85/013 using freshwater and/or marine organisms; wastewater testing by EPA method 1000.0; wastewater testing by EPA method 1002.0; wastewater testing by EPA method 1003.0; wastewater testing by EPA method 1006; wastewater testing by EPA method 1007; wastewater testing by EPA method 1009; wastewater testing according to Anderson, et al. (1990) using Giant Kelp (*Macrocystis pyrifera*); wastewater testing according to Anderson, et al. (1990) using red abalone (*Haliotis rufescens*); wastewater testing according to Dinnel and Stober (1987) using purple sea urchin (*Strongylocentrotus purpuratus*); wastewater testing according to Dinnel and Stober (1987) using red sea urchin (*Strongylocentrotus franciscanus*); wastewater testing according to Dinnel and Stober (1987) using sand dollar (*Dendraster excentricus*);

~~wastewater testing according to procedure E 724-89 (ASTM, 1989) using Pacific oyster (Crassostrea gigas); wastewater testing according to procedure E 724-89 (ASTM, 1989) using California Bay Mussel (Mytilus edulis); wastewater testing according to procedure E 1218-90 (ASTM, 1990) using an alga (skeletonema costatum); wastewater testing according to EPA/600/4-90/027 using freshwater and/or marine organisms.~~

~~(i) Field of Testing 9 consists of those methods whose purpose is to detect physical~~

~~(j) properties of hazardous wastes for regulatory purposes and encompasses the following Subgroups: ignitability; corrosivity by pH determination; corrosivity by corrosivity towards steel; reactivity.~~

~~(k) Field of Testing 10 consists of those methods whose purpose is to detect the presence of inorganic substances in hazardous waste samples and encompasses the following Subgroups: antimony; arsenic; barium; beryllium; cadmium; chromium, total; cobalt; copper; lead; mercury; molybdenum; nickel; selenium; silver, thallium; vanadium; zinc; chromium (VI); cyanide; fluoride; sulfide; total organic lead.~~

~~(l) Field of Testing 11 consists of those methods whose purpose is to prepare samples of hazardous wastes for further testing and encompasses the following Subgroups: California waste extraction test (WET); extraction procedure toxicity (EP TOX); toxicity characteristic leaching procedure (TCLP), all phases; TCLP, extraction of inorganics only; TCLP, extraction of semivolatile organics only; TCLP, extraction of volatile organics only.~~

~~(m) Field of Testing 12 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8240 for volatile compounds; EPA method 8250 for semivolatile compounds; EPA method 8270 for semivolatile compounds; EPA method 8280 for dioxins, EPA method 8290, EPA method 8260.~~

~~(n) Field of Testing 13 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8010 for halogenated volatiles; EPA method 8015 for nonhalogenated volatiles; EPA method 8020 for aromatic volatiles; EPA method 8030 for acrolein, acrylonitrile, acetonitrile; EPA method 8040 for phenols; EPA method 8060 for phthalate esters; EPA method 8080 for organochlorine pesticides or polychlorinated biphenyls; EPA method 8090 for nitroaromatics and cyclic ketones; EPA method 8100 for polynuclear aromatic hydrocarbon; EPA method 8130 for polynuclear aromatic hydrocarbons; EPA method 8120 for chlorinated hydrocarbons; EPA method 8140 for organophosphorus pesticides; EPA method 8150 for chlorinated herbicides; EPA method 632 for carbamates; total petroleum hydrocarbons—gasoline (LUFT manual); total petroleum hydrocarbons—diesel (LUFT manual); EPA method 8011; EPA method 8021; EPA method 8070; EPA method 8110; EPA method 8141; EPA method 8330; EPA method 8080 for PCBs only; EPA method 8080 for chlorinated pesticides only.~~

~~(o) Field of Testing 14 consists of those methods whose purpose is to detect the presence of asbestos for purposes of complying with the provisions of Title 22, California Code of Regulations, Section 66261.24(a)(92)(A) and encompasses the following Subgroups: asbestos by polarized light microscopy.~~

~~(p) Field of Testing 15 shall be any method whose purpose is to detect the presence of any analyte found in the list of substances regulated by the California Safe Drinking Water and Toxic Enforcement Act in drinking water, wastewater, hazardous wastes, and contaminated soils or sediments, but which method is not within any subgroup of any other Field of Testing cited in this section.~~

~~(q) Field of Testing 16 consists of those methods whose purpose is to detect the presence of inorganic substances, nutrients, physical or chemical demands, or physical properties in the determination of wastewater quality, and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic techniques and encompasses the following Subgroups: acidity; alkalinity (includes determination of~~

bicarbonate, carbonate, & hydroxide); ammonia; biochemical oxygen demand (BOD); boron; bromide; calcium (titrimetric technics); carbonaceous biochemical oxygen demand (cBOD); chemical oxygen demand (COD); chloride; chlorine residual, total; cyanide; cyanide amenable to chlorination; fluoride; hardness (direct determination); kjeldahl nitrogen (includes determination of organic nitrogen); magnesium (titrimetric technics); nitrate; nitrite; oil and grease; organic carbon; oxygen, dissolved, pH; phenols; phosphate ortho; phosphorus, total; potassium (flame emission technics); residue, total; residue, filterable (total dissolved solids); residue, nonfilterable (total suspended solids); residue, settleable (settleable solids); residue, volatile; silica; sodium (flame emission technics); specific conductance; sulfate; sulfide (includes total and soluble); sulfite; surfactants (MBAs); tannin and lignin; turbidity; iron; manganese; total recoverable hydrocarbons by EPA method 418.1; total organic halides.

(r) Field of Testing 17 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of wastewater quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: aluminum; antimony; arsenic; barium; beryllium; cadmium; chromium (VI); chromium, total; cobalt; copper; gold; iridium; iron; lead; manganese; mercury; molybdenum; nickel, osmium; palladium; platinum; rhodium; ruthenium; selenium; silver; strontium; thallium; tin; titanium; vanadium; zinc; asbestos; calcium; magnesium; potassium; sodium.

(s) Field of Testing 18 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 624 for volatile organics; EPA method 625 for acid and base/neutral compounds; EPA method 1613 for dioxins; EPA method 1625 for dioxins; EPA method 613.

(t) Field of Testing 19 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and do not

~~require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 601 for halogenated volatiles; EPA method 602 for aromatic volatiles; EPA method 603 for acrolein, acrylonitrile, acetonitrile; EPA method 604 for phenols; EPA method 605 for benzidine; EPA method 606 for phthalate esters; EPA method 607 for nitrosoamines; EPA method 608 for organochlorine pesticides or polychlorinated biphenyls; EPA method 609 for nitroaromatics and cyclic ketones; EPA method 610 for polynuclear aromatics; EPA method 612 for haloethers; EPA method 632 for carbamates; EPA method 619; EPA method 608 for PCBs only; EPA method 608 for chlorinated pesticides only.~~

~~(u) Field of Testing 20 consists of those methods whose purpose is to detect the presence of inorganic pesticide residues in raw agricultural or bulk processed food and encompasses the following Subgroups: pesticide residues in processed foods detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric techniques; pesticide residues in raw commodities detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric techniques; pesticide residues in dairy products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric techniques; pesticide residues in feed products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric techniques.~~

~~(v) Field of Testing 21 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: chromatographic/mass spectrophotometric methods in either processed foods; raw commodities; dairy products; feed products.~~

~~(w) Field of Testing 22 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and do not require the use of a gas chromatographic/mass spectrophotometric device and~~

~~encompass the following Subgroups: halogenated compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in raw commodities detected by either gas chromatograph, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics.~~

~~(x) Field of Testing 23 consists of the subgroup members appropriate to the Field of Testing stated by the laboratory, pursuant to Section 64805(b)(1).~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference:  
Sections 1012, 1013, 1015, 1017 and 1019, Health and Safety Code.~~

**Repeal Article 13 as follows:**

**~~Article 13. Trade Secrets.~~**

~~Section 64825. Trade Secrets.~~

~~(a) If a laboratory identifies information provided to the Department as a trade secret, the Department shall not release such information unless:~~

~~(1) the release is authorized under state or federal law; and~~

~~(2) the Department has notified the laboratory of the impending release.~~

~~Such notification shall be at least ten days prior to releasing any information identified as a trade secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Sections 1012 and 1013, Health and Safety Code; Section 6254.7(d),  
Government Code.~~

**Repeal Article 14 as follows:**

**~~Article 14. Sale or Transfer of Ownership of a Laboratory.~~**

~~Section 64827. Sale or Transfer of Ownership.~~

~~(a) A certificate shall be voided by operation of law if one or more of the following occurs.~~

~~(1) An original Owner fails to notify the Department, in writing, within 15 days after a change in ownership.~~

~~(2) A new Owner relocates the laboratory within 90 days of assuming ownership.~~

~~(3) If more than half the number of laboratory persons either quit or are terminated and replaced by a new Owner within 90 days of assuming ownership.~~

~~(4) If a new Owner submits an application to alter the laboratory's certificate as issued to the prior Owner by the addition of any Subgroup within any Field of Testing.~~

~~(b) A new Owner of a laboratory shall notify the Department, in writing, within 15 days after the sale or transfer of ownership and provide, at minimum, the following information.~~

~~(1) The name(s) of the new Owner(s).~~

~~(2) The date of sale or transfer of ownership.~~

~~(3) The name, education and laboratory related work experiences, as specified in Section 64817(a); or voluntary laboratory certificate grade as specified in Section 64817(b), of the person designated as the Laboratory Director.~~

~~(4) The names, education and laboratory related work experiences, as specified in Section 64817(g); or voluntary laboratory certificate grade as specified in Section 64817(h), of all persons who are designated as Principal Analysts.~~

~~(5) The names of all Principal Analysts who have quit, or were terminated and replaced; and the names of all Principal Analysts hired as replacements.~~

~~(6) A statement that there will be no changes in laboratory location, or in the certificate issued to the prior Owner(s) within 90 days of assuming ownership.~~

~~(7) A statement that all equipment, method, and quality assurance practices will not change within 90 days of assuming ownership.~~

~~(8) The notice shall be signed by one or more of the new Owner(s), or their Agents.~~

~~(c) New Owners that comply with the provisions of (b) above shall have use of the certificate issued to the prior Owner for a period of ninety days commencing with the date of the Department's notice of receipt of the information supplied by the new Owner.~~

~~(1) The certificate number and the laboratory name appearing on the certificate shall remain the same.~~

~~(2) The new Owner shall display, and provide a copy with all data reports, the Department's notice recognizing the sale or transfer of ownership.~~

~~(d) To obtain the use of the certificate to its original expiration date, the new Owner shall request such use in writing, and the laboratory shall be subjected to, and pass the following, within the 90 days use period granted by the Department.~~

~~(1) A site visit in accordance with Section 64807; and~~

~~(2) Performance evaluation samples in accordance with Section 64809.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code.~~

~~Reference: Section 1014, Health and Safety Code.~~

**Repeal Article 16 as follows:**

**~~Article 16. National Environmental Laboratory Accreditation Program (NELAP)~~**

~~Section 64860. NELAP Accreditation Fees.~~

~~(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal of a National Environmental Laboratory Accreditation Program (NELAP) primary or secondary accreditation:~~

~~(1) A non-refundable application fee of \$3,000 payable at the time of initial and renewal application for accreditation, and~~

~~(2) An additional non-refundable fee for each Field of Testing specified in Health and Safety Code Section 100862 which the laboratory has requested in its~~

~~application, payable at the time of application for an initial, amended, or renewed NELAP accreditation, as follows:~~

~~(A) A fee of \$750 for each low complexity Field of Testing, identified as Fields of Testing number N115, N120, and N121.~~

~~(B) A fee of \$1000 for each medium complexity Field of Testing, identified as Field of Testing number N101, N102, N103, N106, N107, N108, N109, N112, N114, and N118.~~

~~(C) A fee of \$1,800 for each high complexity Field of Testing, identified as Field of Testing number N104, N105, N110, N111, N113, N116, N117 and N119.~~

~~(b) No environmental laboratory shall be approved as a NELAP accredited laboratory until fees provided by this section have been paid.~~

~~Note: Authority cited: Sections 100830, 100835(a) and 100862, Health and Safety Code. Reference: Section 100825, Health and Safety Code.~~